IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

ALLERGAN, INC. and DUKE UNIVERSITY, **Plaintiffs,** **v.** **APOTEX INC. and APOTEX CORP.,** **Defendants.**	**Civil Action No. 1:10-CV-681** **JURY TRIAL DEMANDED**

COMPLAINT FOR PATENT INFRINGEMENT

For their Complaint against Defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex" or "Defendants"), Plaintiffs Allergan, Inc. ("Allergan") and Duke University (collectively with Allergan, "Plaintiffs"), by their attorneys, allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent Nos. 7,351,404 ("the '404 patent"), 7,388,029 ("the '029 patent"), and 6,403,649 ("the '649 patent") under 35 U.S.C. § 271(e)(2) relating to Allergan's commercially successful hypotrichosis treatment, Latisse®.

THE PARTIES

2. Allergan is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 2525 Dupont Drive, Irvine, California 92612.

3. Duke University is an educational, research and healthcare institution and a North Carolina nonprofit corporation located in Durham, North Carolina.

4. On information and belief, Defendant Apotex Inc. is a corporation organized and existing under the laws of Canada, with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

5. On information and belief, Defendant Apotex Inc. manufactures numerous generic drugs for sale and use throughout the United States, including this judicial district.

6. On information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida, 33326.

7. On information and belief, Defendant Apotex Corp. is a subsidiary of Apotex, Inc.

JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, *et seq*. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331 and 1338.

9. This Court has personal jurisdiction over Apotex by virtue of its systematic and continuous contacts with this jurisdiction, as alleged herein, as well as because of the injury to Plaintiffs, and the cause of action Plaintiffs have raised, as alleged herein.

10. Specifically, this Court has personal jurisdiction over Defendants Apotex Inc. and Apotex Corp. because they, either directly or through an agent, including each other, regularly do or solicit business in this jurisdiction, engage in other persistent courses of conduct in this jurisdiction, and/or derive substantial revenue from services or things used or consumed in this jurisdiction.

11. On information and belief, Apotex Inc. and Apotex Corp. are agents of each other and/or work in active concert with respect to the development, regulatory approval, marketing, sale and distribution of pharmaceutical products, including the generic Bimatoprost Topical Solution 0.03% described in ANDA No. 201894 (defined below).

12. Further demonstrating the close interconnections between the two entities is the fact that both Apotex Inc. and Apotex Corp. provided Plaintiffs with notice, via a single letter, that the two entities had submitted a new drug application for bimatoprost topical solution 0.03% to the United States Food and Drug Administration ("FDA").

13. On information and belief, Defendant Apotex Corp. is a licensed drug wholesaler in North Carolina.

14. On information and belief, Defendant Apotex Corp. is on the list of Active Drug Rebate Labelers issued by the North Carolina Department of Health and Human Services.

15. On information and belief, an officer of Defendant Apotex Corp. has attended multiple meetings held by the North Carolina Board of Pharmacy on behalf of Apotex Corp.

16. On information and belief, Defendant Apotex Inc.'s drug products are listed on relevant North Carolina formulary(ies).

17. On information and belief, Apotex Corp. sells numerous generic drugs, manufactured and supplied by Apotex Inc., throughout the United States, including this judicial district.

18. On information and belief, in 2009 Apotex Corp. sold over $348 million worth of Apotex Inc.'s products in North Carolina, over $51 million of which were sold in this judicial district.

19. On information and belief, Defendant Apotex Inc. has brought lawsuits in this judicial district against other drug manufacturers.

20. On information and belief, Defendant Apotex Inc. filed suit against Eisai Inc. and Eisai Co., Ltd. on July 1, 2009 in this judicial district, Case No. 1:09-CV-00477. The suit is currently pending.

21. On information and belief, Defendant Apotex Inc. filed suit against Glaxo Wellcome Inc. and SmithKline Beecham Corporation, d/b/a GlaxoSmithKline, on July 6, 2009 in this judicial district, Case No. 1:09-CV-00485.

22. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

23. The '404 patent, entitled "Method of Enhanced Hair Growth," issued to David F. Woodward and Amanda M. VanDenburgh on April 1, 2008. A copy of the '404 patent is attached to this Complaint as Exhibit A.

24. Allergan, as assignee, owns the entire right, title, and interest in the '404 patent.

25. The '029 patent, entitled "Compositions and Methods for Treating Hair Loss Using Non-Naturally Occurring Prostaglandins," issued to Mitchell Anthony DeLong, John McMillan McIver, and Robert Scott Youngquist on June 17, 2008. A copy of the '029 patent is attached to this complaint as Exhibit B.

26. Duke University, as assignee, owns the entire right, title, and interest in the '029 patent.

27. Allergan is an exclusive field licensee of the '029 patent.

28. The '649 patent, entitled "Non-Acidic Cyclopentane Heptanoic Acid,2-Cycloalkyl Or Arylalkyl Derivatives As Therapeutic Agents," issued to David F. Woodward, Steven W. Andrews, Robert M. Burk, and Michael E. Garst. A copy of the '649 patent is attached to this Complaint as Exhibit C.

29. Allergan, as assignee, owns the entire right, title, and interest in the '649 patent.

30. Allergan is the holder of an approved New Drug Application ("NDA") No. 22-369 for bimatoprost topical solution/drops, 0.03%, sold under the Latisse® registered trademark.

31. In conjunction with that NDA, Allergan has listed with the FDA three patents (the "Listed Patents") that cover the approved formulation of Latisse®. The Listed Patents are the '404,'029, and '649 patents. The FDA has published the Listed Patents in the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book."

32. Latisse® is covered by at least one claim of each of the Listed Patents.

33. On or about July 27, 2010, Plaintiffs received a letter, dated July 26, 2010, signed on behalf of Apotex Inc. and Apotex Corp. by Kiran Krishnan for Bernice Tao, Director of Regulatory Affairs, Apotex, Inc. On information and belief, Kiran Krishnan is Associate Director of Regulatory Affairs at Apotex Corp.

34. The July 26, 2010 letter stated that Apotex Inc. and Apotex Corp. had submitted, and the FDA had received, an Abbreviated New Drug Application ("ANDA") under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), seeking approval to engage in the commercial manufacture, use, importation, offer for sale or sale of Bimatoprost Topical Solution 0.03%, a generic version of Allergan's Latisse® product, prior to expiration of the '404 and '029 patents. The ANDA Number for Apotex's application is 201894.

35. The July 26, 2010 letter stated that the '404 and '029 patents were invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use or sale of Apotex's proposed Bimatoprost Topical Solution 0.03%.

36. Attached to the July 26, 2010 letter was a statement of the factual and legal bases for Apotex's Paragraph IV certifications that the '404 and '029 patents are invalid, unenforceable, or will not be infringed by the manufacture, use, importation, sale or offer for sale of Apotex's proposed Bimatoprost Topical Solution 0.03%.

37. The July 26, 2010 letter also stated that the '649 patent was "not relevant," but did not articulate why the '649 patent was irrelevant. Counsel for Allergan has inquired with Apotex as to the reasons for this statement. As of the date of this complaint, Apotex has not confirmed the basis for the statement.

38. In filing its ANDA No. 201894, Apotex has requested the FDA's approval to market a generic version of Allergan's Latisse® product throughout the United States, including in North Carolina.

39. On information and belief, following FDA approval of its ANDA No. 201894, Apotex will sell the approved generic version of Allergan's Latisse® product throughout the United States, including in North Carolina.

COUNT I

(Infringement of the '029 Patent Under 35 U.S.C. § 271(e)(2) by Apotex's Proposed Generic Bimatoprost Topical Solution 0.03%)

40. Paragraphs 1 to 39 are incorporated herein as set forth above.

41. Apotex submitted ANDA No. 201894 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale or importation of its proposed generic Bimatoprost Topical Solution 0.03% throughout the United States. By submitting this application, Apotex has committed an act of infringement of the '029 patent under 35 U.S.C. § 271(e)(2)(A).

42. The commercial manufacture, use, offer for sale, sale and/or importation of Apotex's proposed generic Bimatoprost Topical Solution 0.03% will constitute an act of direct infringement of the '029 patent.

43. On information and belief, Apotex became aware of the ’029 patent no later than when it submitted ANDA No. 201894 to the FDA, in which it identified the ’029 patent as one of the patents covering the approved formulation of Latisse®.

44. On information and belief, Apotex knew or should have known that its commercial manufacture, use, offer for sale, sale and/or importation of its proposed generic Bimatoprost Topical Solution 0.03% will actively induce the actual infringement of the ’029 patent.

45. On information and belief, Apotex knew or should have known that its proposed generic Bimatoprost Topical Solution 0.03% will be especially made or especially adapted for use in an infringement of the ’029 patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale and/or importation of its proposed generic Bimatoprost Topical Solution 0.03% will actively contribute to the actual infringement of the ’029 patent.

46. The commercial manufacture, use, offer for sale, sale and/or importation of Apotex’s proposed generic Bimatoprost Topical Solution 0.03% in violation of Plaintiffs’ patent rights will cause harm to Plaintiffs for which damages are inadequate.

COUNT II

(Infringement of the ’404 Patent Under 35 U.S.C. § 271(e)(2) by Apotex’s Proposed Generic Bimatoprost Topical Solution 0.03%)

47. Paragraphs 1 to 46 are incorporated herein as set forth above.

48. Apotex submitted ANDA No. 201894 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale or importation of its proposed generic Bimatoprost Topical Solution 0.03% throughout the United

States. By submitting this application, Apotex has committed an act of infringement of the '029 patent under 35 U.S.C. § 271(e)(2)(A).

49. The commercial manufacture, use, offer for sale, sale and/or importation of Apotex's proposed generic Bimatoprost Topical Solution 0.03% will constitute an act of direct infringement of the '404 patent.

50. On information and belief, Apotex became aware of the '404 patent no later than when it submitted ANDA No. 201894 to the FDA, in which it identified the '404 patent as one of the patents covering the approved formulation of Latisse®.

51. On information and belief, Apotex knew or should have known that its commercial manufacture, use, offer for sale, sale and/or importation of its proposed generic Bimatoprost Topical Solution 0.03% will actively induce the actual infringement of the '404 patent.

52. On information and belief, Apotex knew or should have known that its proposed generic Bimatoprost Topical Solution 0.03% will be especially made or especially adapted for use in an infringement of the '404 patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale and/or importation of its proposed generic Bimatoprost Topical Solution 0.03% will actively contribute to the actual infringement of the '404 patent.

53. The commercial manufacture, use, offer for sale, sale and/or importation of Apotex's proposed generic Bimatoprost Topical Solution 0.03% in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

COUNT III

(Infringement of the '649 Patent Under 35 U.S.C. § 271(e)(2) by Apotex's Proposed Generic Bimatoprost Topical Solution 0.03%)

54. Paragraphs 1 to 53 are incorporated herein as set forth above.

55. Apotex submitted ANDA No. 201894 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale or importation of its proposed generic Bimatoprost Topical Solution 0.03% throughout the United States. By submitting this application, Apotex has committed an act of infringement of the '649 patent under 35 U.S.C. § 271(e)(2)(A). To the extent Apotex has filed a certification with the FDA that it does not seek approval of ANDA No. 201894 before the expiration of the '649 patent, Apotex has not informed Allergan of that fact. Instead, Apotex's July 26, 2010 letter simply states that the '649 patent is "not relevant" to Apotex's ANDA. As of the date of this complaint, Apotex has not confirmed the basis for the statement that the '649 patent is "not relevant."

56. The commercial manufacture, use, offer for sale, sale and/or importation of Apotex's proposed generic Bimatoprost Topical Solution 0.03% will constitute an act of direct infringement of the '649 patent.

57. On information and belief, Apotex became aware of the '649 patent no later than when it submitted ANDA No. 201894 to the FDA, in which it identified the '649 patent as one of the patents covering the approved formulation of Latisse®.

58. On information and belief, Apotex knew or should have known that its commercial manufacture, use, offer for sale, sale and/or importation of its proposed generic Bimatoprost Topical Solution 0.03% will actively induce the actual infringement of the '649 patent.

59. On information and belief, Apotex knew or should have known that its proposed generic Bimatoprost Topical Solution 0.03% will be especially made or especially adapted for use in an infringement of the ’649 patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale and/or importation of its proposed generic Bimatoprost Topical Solution 0.03% will actively contribute to the actual infringement of the ’649 patent.

60. The commercial manufacture, use, offer for sale, sale and/or importation of Apotex’s proposed generic Bimatoprost Topical Solution 0.03% in violation of Allergan’s patent rights will cause harm to Allergan for which damages are inadequate.

JURY TRIAL DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs hereby request a trial by jury of all issues so triable.

PRAYER FOR RELIEF

Plaintiffs respectfully pray for the following relief:

a. That judgment be entered that Apotex has infringed the ’404, ’029, and the ’649 patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 201894 under section 505(j) of the Federal Food, Drug, and Cosmetic Act, and that the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of Apotex’s proposed generic Bimatoprost Topical Solution 0.03% will constitute an act of infringement of the ’404,’029, and ’649 patents;

b. That an Order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Apotex’s ANDA No. 201894 shall be a date which is not earlier than the

expiration date of the ’404,’029, and ’649 patents, as extended by any applicable period of exclusivity;

c. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Apotex, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by the ’404, ’029, and/or ’649 patents;

d. If Apotex attempts to engage in the commercial manufacture, use, offer to sell, sale or importation of Apotex’s generic product disclosed in its ANDA No. 201894 prior to the expiration of the ’404, ’029, and ’649 patents, as extended by any applicable period of exclusivity, a preliminary injunction be entered enjoining such conduct;

e. If Apotex attempts to engage in the commercial manufacture, use, offer to sell, sale or importation of Apotex’s generic product disclosed in its ANDA No. 201894 prior to the expiration of the ’404, ’029, and ’649 patents, as extended by any applicable period of exclusivity, judgment awarding Plaintiffs damages resulting from such infringement under 35 U.S.C. § 271(e)(4)(C), increased to treble the amount found or assessed together with interest pursuant to 35 U.S.C. § 284;

f. That this is an exceptional case under 35 U.S.C. § 285, and that Plaintiffs be awarded reasonable attorneys’ fees and costs;

g. An accounting for infringing sales not presented at trial and an award by the Court of additional damages for any such infringing sales; and

h. That this Court award such other and further relief as it may deem just and proper.

Dated: September 8, 2010

Respectfully submitted,

/s/ Jeffrey D. Patton

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